VAERS

Vaccine Adverse Event Reporting System

http://vaers.hhs.gov

National Childhood Vaccine Injury Act of 1986
Selected provisions

- **Vaccine Adverse Event Reporting System (VAERS)**
  - Accepts reports of adverse events following vaccination

- **Vaccine Information Statements (VIS)**
  - Required for childhood vaccines

- **National Vaccine Injury Compensation Program (NVICP)**
  - Compensates those injured by vaccines on a "no fault" basis

Vaccine Adverse Event Reporting System (VAERS)

- **National spontaneous (or passive) reporting system for adverse events after US-licensed vaccines**
  - Receives ≈ 58,000 reports annually*
  - Accepts reports from healthcare providers, manufacturers and public
  - Signs/symptoms of AE are coded using the Medical Dictionary for Regulatory Activities (MedDRA)± terms and entered into a database
  - Primarily used for signal detection and hypothesis generation
- **Jointly administered by CDC and FDA since 1990**

* 2014-2018
± http://www.meddra.org/

Objectives of VAERS

- **Signal detection/hypothesis generation**
  - Detect new, unusual, or rare vaccine adverse events (AEs)
  - Identify potential risk factors in vaccine recipients for particular types of AEs
  - Monitor trends in known AEs, particularly increased reporting over time
  - Assess the safety of newly licensed vaccines
- **Rapidly respond to vaccine safety concerns or public health emergencies**
  - **Example:** large scale pandemic influenza vaccination program

What to report to VAERS

- **Any medically important health event/adverse event following vaccination (events of concern to provider, patient or family) following immunization even if you are not sure the vaccine caused the event**
  - Local: redness, swelling, pain at injection site
  - Systemic: fever, myalgia, headache
  - Allergic: hives, pruritis, anaphylaxis
  - Vaccination errors (e.g., wrong drug administered)

- **The National Childhood Vaccine Injury Act mandates healthcare providers report specific AEs following vaccination and those contraindicated to receiving another dose of the vaccine**
  - **VAERS Table of Reportable Events**
    https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

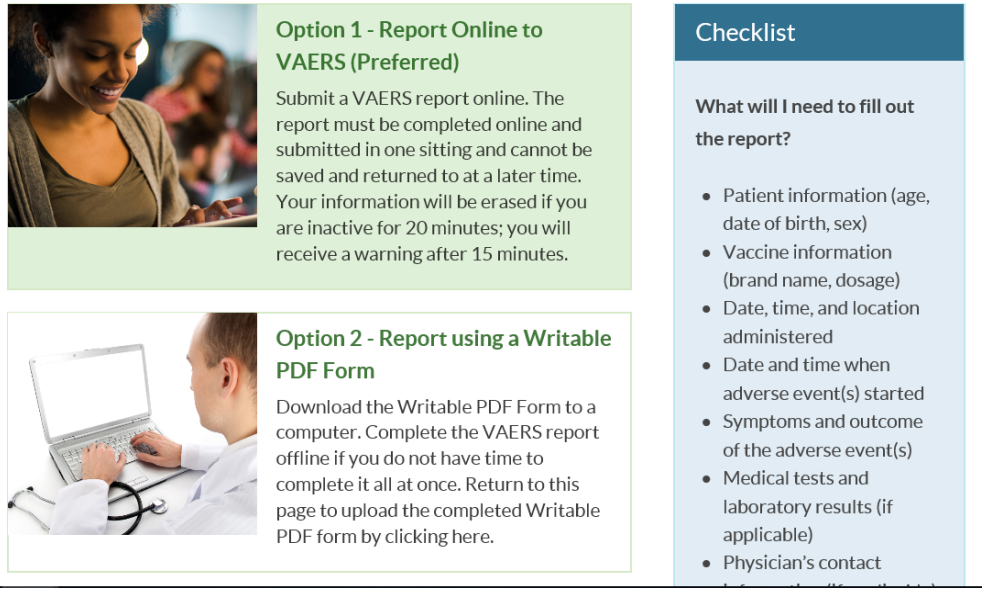
VAERS Table of Reportable Events following vaccination

https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	**Event and interval** from vaccination**
Tetanus in any combination; DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Brachial neuritis (28 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Pertussis in any combination; DTaP, DTP, DTP-Hib, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (7 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Measles, mumps and rubella in any combination; MMR, MMRV, MM	A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (15 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Rubella in any combination; MMR, MMRV	A. Chronic arthritis (42 days) B. Any acute complications or sequelae (including death) of above event (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

How to Report to VAERS: Two Options

1. Report online on the VAERS website (vaers.hhs.gov)
2. Report using a writeable pdf
   - Download the 1 page form
   - Complete and upload into the VAERS website



Vaccine Adverse Event Reporting System (VAERS)

Strengths

- National data
- Accepts reports from anyone
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

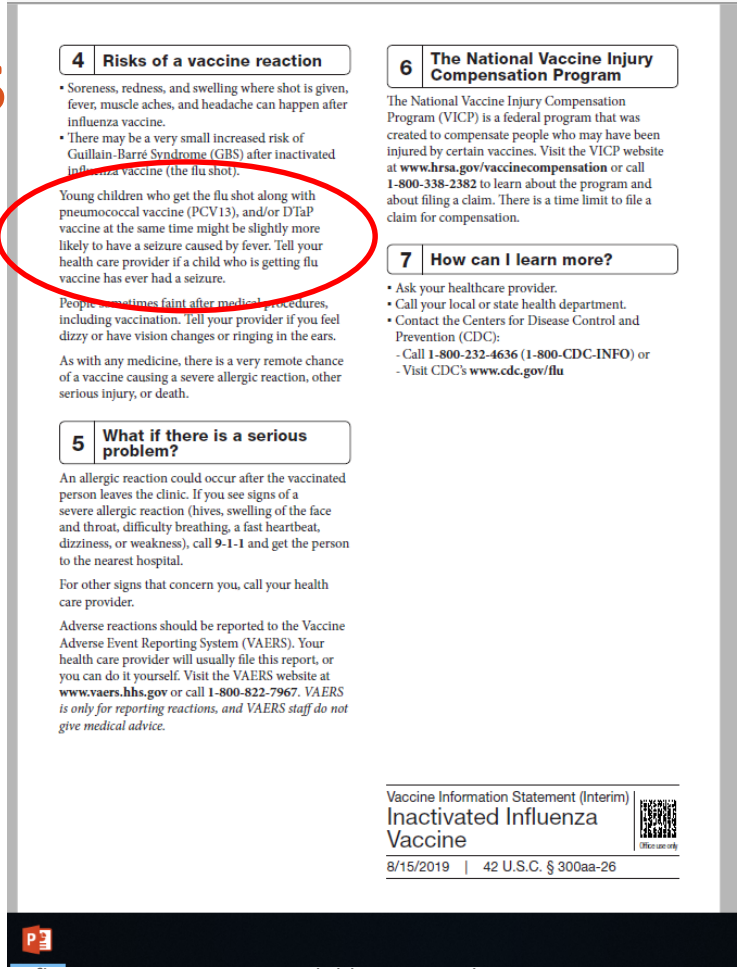
Limitations

- Reporting bias
- Inconsistent data quality and completeness
- Lack of unvaccinated comparison group
- Generally cannot assess causality

- VAERS accepts all reports from all reporters without making judgments on causality or judging clinical seriousness of the event
- As a hypothesis generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

Example of A Signal Found in VAERS

- **Febrile seizures following inactivated influenza vaccine**
  - 2010-2011 influenza season: VAERS detected a febrile seizure signal
  - Signal was further assessed and quantified in other CDC safety systems*
  - Co-administration of inactivated influenza vaccine and pneumococcal conjugate vaccine to young children slightly increased the risk of fever and febrile seizures
- **Findings from CDC's ISO were incorporated into the Vaccine Information Statements (VIS)**



4 Risks of a vaccine reaction

- Soreness, redness, and swelling where shot is given, fever, muscle aches, and headache can happen after influenza vaccine.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13), and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do not give medical advice.*

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

7 How can I learn more?

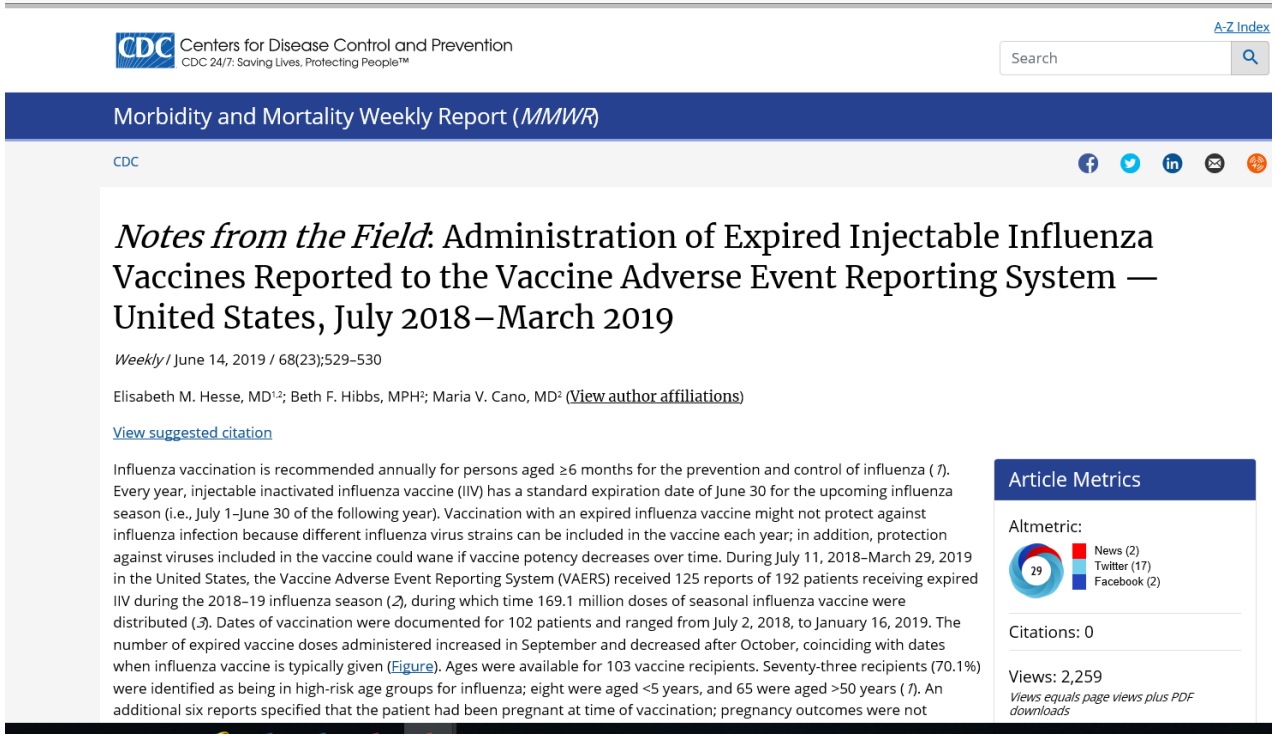
- Ask your healthcare provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's **www.cdc.gov/flu**

Vaccine Information Statement (Interim)
Inactivated Influenza Vaccine
8/15/2019 | 42 U.S.C. § 300aa-26

*Broder et al. In the heat of a signal: responding to a vaccine safety signal for febrile seizures after 2010-11 influenza vaccine in young children, United States. Vaccine. 2012 Mar 2;30(11):2032-4

Another Example of A Signal Found in VAERS

- Administration of expired flu vaccine



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Morbidity and Mortality Weekly Report (*MMWR*)

CDC

Notes from the Field: Administration of Expired Injectable Influenza Vaccines Reported to the Vaccine Adverse Event Reporting System — United States, July 2018–March 2019

Weekly / June 14, 2019 / 68(23);529–530

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Influenza vaccination is recommended annually for persons aged ≥6 months for the prevention and control of influenza (*1*). Every year, injectable inactivated influenza vaccine (IIV) has a standard expiration date of June 30 for the upcoming influenza season (i.e., July 1–June 30 of the following year). Vaccination with an expired influenza vaccine might not protect against influenza infection because different influenza virus strains can be included in the vaccine each year; in addition, protection against viruses included in the vaccine could wane if vaccine potency decreases over time. During July 11, 2018–March 29, 2019 in the United States, the Vaccine Adverse Event Reporting System (VAERS) received 125 reports of 192 patients receiving expired IIV during the 2018–19 influenza season (*2*), during which time 169.1 million doses of seasonal influenza vaccine were distributed (*3*). Dates of vaccination were documented for 102 patients and ranged from July 2, 2018, to January 16, 2019. The number of expired vaccine doses administered increased in September and decreased after October, coinciding with dates when influenza vaccine is typically given (Figure). Ages were available for 103 vaccine recipients. Seventy-three recipients (70.1%) were identified as being in high-risk age groups for influenza; eight were aged <5 years, and 65 were aged >50 years (*1*). An additional six reports specified that the patient had been pregnant at time of vaccination; pregnancy outcomes were not

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